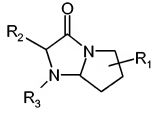
RESPONSE AND ARGUMENT

Restriction. The Office Action dated August 31, 2006 asserts the existence of two inventions:

I, etc. Claims 1-49, drawn to a compound having the structure of formula I, as in claim 1, classifiable in class 514, subclass 249.

II, etc. Claims 50-56, drawn to a method of altering a disorder or condition associated with the activity of a Melanocortin receptor, comprising administering to a patient a therapeutically effective amount of the composition of claim 49 (i.e., a composition of "any of the foregoing structure"), classified in class 514, subclass 19.

Election of Invention. Applicants elect the invention of Group I, etc., claims 1 - 49. The election of Group I itself is without traverse. With respect to the assertion that Group I is "further divided into multiple groups each representing a different molecular core ring structure..." (Page 3 of Office Action), Applicants provisionally elect with traverse that invention of Group I wherein **z** is 0 and **X** is C=O, such that "molecular core ring structure" is:

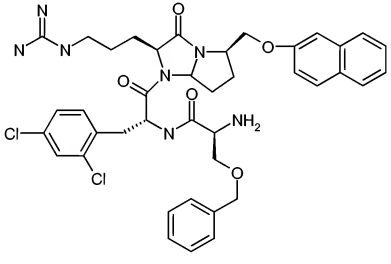


Applicants understand the restriction requirement to only require restriction to a single "different molecular core ring structure." See page 3 of Office Action, the paragraph starting "In addition each of ..." Thus Applicants assert that the election of the foregoing molecular core ring structure is fully responsive to the restriction under 35 U.S.C. § 121.

Applicants note that the Office Action further states that the "inventions are distinct" for reasons given on pages 3 - 4 of the Office Action, which reasons do not relate to the "core ring structure" but which instead relate to ring structures in pendant groups. However, Applicants further note that the Office Action provides that the "elected compound must provide values for

the variables for **J**, **W**, **Q**, and **z**, which define the elected core ring structure." Applicants traverse the requirement that election of the variables for **J**, **W**, **Q**, and **z** are required for restriction under 35 U.S.C. § 121. However, in order to comply with the provisional election requirement of 37 C.F.R. § 1.143, Applicants provisionally elect as follows: wherein **J** comprises a naphthyl ring, wherein **W** is a heteroatom unit with at least one cationic center, hydrogen bond donor or hydrogen bond acceptor wherein at least one atom is N, on the proviso that **W** does not comprise a ring structure, wherein **Q** comprises substituted phenyl, and wherein **z** is 0.

Election of Species. With respect to the requirement of election of a species, and in compliance with 37 C.F.R. § 1.146, Applicants elect the species as disclosed in Example 45. Applicants note that Example 45 describes the R_3 group as "Ser(Bzl)-D-Phe(2,4-diCl)-". In order to facilitate search and examination, Applicants provide the following structure, substituting the complete molecular structure for those portions depicted in Example 45 by way of named amino acid residues:



The foregoing compound has the name, as generated using the Autonom 2000 feature of MDL ISIS/Draw 2.5, (S)-2-amino-3-benzyloxy-N-[(R)-1-(2,4-dichloro-benzyl)-2-[(3S,6R)-3-(3-guanidino-propyl)-6-(naphthalen-2-yloxymethyl)-4-oxo-2,5-diaza-spiro[4.4]non-2-yl]-2-oxo-ethyl]-propionamide.

The following claims are readable on the elected species: 1, 2, 4, 6, 8, 9, 12, 14, 16, 18, 20, 21, 23, 25, 27, 28, 31, 33, 35, 37, 39, 40, 42, 44, 46, and 48.

Traversal and Request for Reconsideration Pursuant to 37 C.F.R. § 1.143. As discussed above, Applicants do not traverse the restriction requirement as to Group I (compound) over Group II (method). However, Applicants do traverse the requirement that Group I be further restricted to one of an asserted multiplicity of separate inventions the variables for **J**, **W**, **Q**, and **z**.

It is clear that all of the inventions of Group I are linked together, and that claims 1, 20 and 39 (independent claims within Group I) are each a genus claim which link all inventions. See MPEP § 809.03. For example, the elected species is readable on each of independent claims 1, 20 and 39. As set forth in MPEP § 809.03, if allowed, linked claims "act to prevent restriction between inventions that can otherwise be shown to be divisible." Id. Thus the proper course of conduct is as set forth in MPEP § 809.03, and to not require election of a single asserted invention, but rather to proceed as provided in ¶ 8.12.

It is further noted that, as provided in MPEP § 818.03(d), if the office allows a linking type claim, the office "is bound to withdraw the requirement and to act on all linked inventions."

The decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), provide that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. See also *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Under the *In re Harnisch* test for "unity of invention", the issue is whether the compounds have a common utility and as a whole have a substantial structural similarity. It is asserted that both conditions are met. With respect to common utility, while a number of different disorders or conditions are asserted in dependent claims 51 to 56 (e.g., eating disorder, cachexia, obesity, sexual dysfunction), each of these is asserted to be "associated with the activity of a melanocortin receptor", as is set forth in claim 50. Indeed, each of claims 51 to 56 depend from claim 50, and

thus by definition each have an etiology associated with activity of a melanocortin receptor. In the absence of the teaching of this application and other literature specific to melanocortin receptors, it might be possible to assert that, for example, cachexia and sexual dysfunction have a different etiology. See Office Action at Page 7, paragraph numbered 6. However, this assertion ignores the functional role that has been ascribed to melanocortin receptors. See specification at page 1, line 27 bridging page 2, line 16, and again at page 19, line 17 bridging page 20, line 24. Because each of the compounds is asserted to have a utility "associated with the activity of a melanocortin receptor", it is apparent that the each of the inventions have a common utility. Similarly, with respect to "substantial structural similarity", it is asserted that the same is clearly present. The "core" ring structure is as set forth above on page 18: there are only two variables, **z**, which is either 0 or 1, and **X**, which is either CH_2 or C=O. Thus the core ring structure is narrowly and specifically drawn. With respect to the pendent groups, R_1 includes only 7 different linkers and a **J** group, where J is a one of a specified number of ring structures; R_2 is of the structure $(CH_2)_y$-W, where W is a specifically defined heteroatom unit; and R_3 has one of 10 different linkers, with an optional amine capping group, amino acid residue or amino acid residue with an amine capping group, and a **Q** group, defined as phenyl, substituted phenyl, naphthyl or substituted naphthyl. It is submitted that this comprises a "substantial structural similarity" among all the inventions. It is further submitted that independent claim 20, which omits the **z** variable (i.e., where **z** is 0) and independent claim 39, which further provides a phenylalanine in the R_3 position, with an optional R_4 group provided, are even narrower, and that perforce all inventions have a "substantial structural similarity."

Additionally, as is provided in MPEP § 803.02, no showing has been made that a search and examination of the entire claim cannot be made without serious burden. As provided in MPEP § 803, the examiner must show a serious burden, such as a *prima facie* showing of separate classification, separate status in the art or a different field of search as defined in MPEP § 808.02. However, here the only showing is that all claims of Group I (claims 1 to 49) are classifiable in class 514, subclass 249. There is no showing or assertion of any separate status

in the art or different field of search with respect to the distinct inventions asserted to be included within Group I. In the absence of any such showing, the presumption is that examination can be made without serious burden.

Applicants specifically reserve their right to petition from the requirement for restriction, in accord with 37 C.F.R. § 1.144.

Conclusion. Applicants respectfully request that the restriction be limited to Group I, and that there not be any requirement with respect to restriction as to other asserted inventions, each of which are linked by one or more generic claims. Examination should proceed on the elected species, with the search extended on the Markush-type claims upon allowance of the elected species.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 50-3582.

Respectfully submitted,

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